

REMARKS

Reexamination and reconsideration is respectfully requested in light of the foregoing amendments to the claims and the following remarks.

Claims 1-36 are pending in this application. Claims 13-24 have been withdrawn from consideration due to a restriction requirement. No new claims have been added. Claims 1, 11 and 34 have been amended. Claim 1 has been amended to clarify "Formula I", to further define R^2 and NR^6 , and to delete the phrase "provided if R^6 is directly bonded to Z, then R^6 is not hydrogen;" No new matter has been added to the application. Support for the amendments can be found at paragraph [0021] and Examples 31-48 of the specification. Further support can be found in original claim 2 as filed and in paragraph [0033] of the published Application No. 2005/0101616, which corresponds to the present application as filed. Claims 11 and 34 have been amended to add a period at the end of each claim.

Applicant notes the Examiner's consideration of the information cited in the Information Disclosure Statements filed March 12, 2004 and April 2, 2004, as acknowledged in the Office Action Summary.

Rejection Under 35 U.S.C. § 112

Claims 1-12 and 25-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite on grounds a) through h) below. The legal standard for indefiniteness is whether a claim reasonably appraises those of skill in the art of its scope. *See Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir.), *cert. denied sub nom., Genetics Inst., Inc. v. Amgen, Inc.*, 112 S.Ct. 169 (1991). The definiteness of the language employed must be analyzed, not in a vacuum, but always in light of the teachings of the

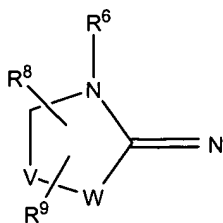
prior art and the application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *See In re Angstadt*, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976).

a) The Examiner states that the recitation “an R^4 group and an R^6 group may be independently joined to complete a 3 to 10 membered cyclic ring ...” in claims 1 and 9 is indefinite because it is unclear whether R^4 and R^6 must be connected to the same atom (e.g., NR^4R^6) or to different atoms (e.g., $NR^4C(O)R^6$) and still form a ring, and in the case where there are two R^4 groups (e.g., $NR^4C(O)NR^4R^6$), it is unclear which of the R^4 groups could form a ring with R^6 . The Examiner further states that since R^4 and R^6 appear in the definitions of A and R^3 , it is unclear if the R^4 of A could form a ring with the R^6 or R^3 , which would fuse with the quinazoline core to give a tricyclic system. It is Applicant’s position that phrase at issue clearly defines the metes and bounds of the invention, and both spirocyclic, fused bicyclic, and tricyclic ring systems are included in the scope of the invention. It is well settled that if the scope of the subject matter embraced by a claim is clear, and if the Applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

b) The Examiner states that the recitation “an R^6 group and an R^8 group may be independently joined to complete a 3 to 10 membered cyclic ring ...” in claims 1 and 10 is indefinite because it is unclear if a spirocycle is formed or an ortho-fused bicyclic system is formed. It is asserted that phrase at issue clearly defines the metes and bounds of the invention, and both spirocyclic and a fused bicyclic ring systems are intended to be included in this term. It is well settled that if the scope of the subject matter embraced by a claim is clear, and if the

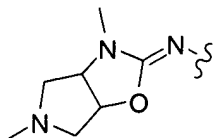
applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention. It is Applicant's position that phrase at issue clearly defines the metes and bounds of the invention, and both spirocyclic and fused bicyclic ring systems are included in the scope of the invention as would be understood by a person having ordinary skill in the art. The Examiner also states the definition of R^6 and R^8 is also unclear because the moieties defined for those variables can also be substituted with OR^6 or NR^6R^8 . The definitions for these substituents is clear. A person having ordinary skill in the art would have understood the metes and bounds of the claims based on the written description of the invention.

c) The Examiner states that the recitation "an R^7 group and an R^8 group may be independently joined to complete a 3 to 10 membered cyclic ring ..." in claims 1 and 11 is indefinite because it is unclear if a spirocycle is formed or an ortho-fused bicyclic system is formed. It is Applicant's position that phrase at issue clearly defines the metes and bounds of the invention, and both spirocyclic and a fused bicyclic ring systems are included in the scope of this invention. For example, the Examiner's attention is directed to Example 44 of the specification as filed, which illustrate one of these ring systems. Specifically, Example 44 shows an example of a compound of claim 1 wherein Z is



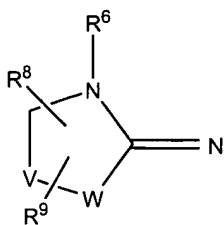
wherein W is O and $V = CR^7R^8$, wherein the ring carbon in the position between the ring nitrogen and the ring V atom is substituted with R^8 . In this example, the R^7 of the V group

together with the R⁸ substituent on the adjacent ring carbon form a fused ring - in this instance a 5 membered fused heterocyclic ring as shown below.

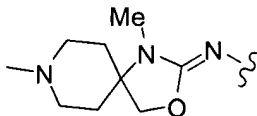


Therefore, it is asserted that the phrase at issue is clear and definite, and withdrawal of this rejection is respectfully requested.

d) The Examiner states that the recitation “an R⁸ group and an R⁹ group may be independently joined to complete a 3 to 10 membered cyclic ring ...” in claims 1 and 12 is indefinite because it is unclear if a spirocycle is formed or an ortho-fused bicyclic system is formed. For example, the Examiner's attention is directed to Example 46 of the specification as filed, which illustrate one of these ring systems. Specifically, Example 46 shows an example of a compound of claim 1 wherein Z is



wherein the ring carbon in the position between the ring nitrogen and the ring V atom is substituted with R⁸ and R⁹, which together form a spirocyclic ring as shown below.



Therefore, it is asserted that the phrase at issue is clear and definite, and withdrawal of this rejection is respectfully requested.

e) The Examiner states that the limitation “solvates” is indefinite because it is unclear what solvent and its ratio are intended. This rejection is respectfully traversed. As stated in paragraph [0045] of the specification as filed (which corresponds to paragraph [0068] of the published patent application), the term “solvate” refers to an aggregate of a molecule with one or more solvent molecules. That is, a solvate can contain either a stoichiometric or nonstoichiometric amount of solvent incorporated within the crystal structure of the compound, and the ratio depends on the solvent, reaction conditions, etc. Accordingly, since a variety of ratios is intended in claim 1, it is asserted that the invention should not be limited by requiring the recitation of a specific ratio of solvent to compound molecule.

Likewise, the definition of “solvate” as provided in the specification as filed is not limited to a specific type of solvent(s), and one of ordinary skill in the art would understand the meaning of this commonly used term. It is well settled that if the scope of the subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention. Thus, it is asserted that the term “solvate” is clear and definite, and applicants should be entitled to claim a solvate of a compound of claim 1 without having to recite a specific solvent or solvents. Withdrawal of this rejection is respectfully requested.

f) The Examiner states that the proviso for R⁶ is unclear because there is no instance where R⁶ is not directly bound to Z. The proviso in claim 1 as originally filed was included to clarify that all R⁶ groups could be hydrogen, with the exception of the R⁶ group bound to the nitrogen atom of the Z group. It is Applicant's position that the proviso as originally filed was

clear and definite. However, in order to expedite prosecution, claim 1 has been amended herein to delete the proviso “provided if R^6 is directly bonded to Z, then R^6 is not hydrogen” and include the proviso “provided that the NR^6 group of Z is not NH”. Support for this amendment can be found in Examples 31-48, for each of which NR^6 is not NH. Accordingly, this amendment to claim 1 does not constitute the addition of new matter. Withdrawal of this rejection is respectfully requested.

g) The Examiner states that claim 2 lacks antecedent basis because it suggests a bicyclic system formed by R^1 and R^2 , which is not recited in claim 1. Claim 1 has been amended herein to include the limitation of claim 2. Support for this amendment can be found in claim 2 as filed and in paragraph [0033] of the published Application No. 2005/0101616, which corresponds to the present application as filed. Withdrawal of this rejection is respectfully requested.

h) Claims 2-12 and 25-35 are rejected as being dependent on claim 1 and carrying over the indefinite limitations. It is Applicant's position that all of the claim rejections with respect to claim 1 have been resolved as discussed above, and therefore the Section 112, second paragraph rejections of the claims which depend therefrom are likewise obviated.

Obviousness-Type Double Patenting Rejection

Claims 1-12 and 25-35 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10, 20-91 and 101-106 of copending Application No. 10/914,974. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed formula I overlaps with formula I of 10/914,974 when their variables represent the following:

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- i. A is Z (of $-(U)_nZ$; $n = 0$);
- ii. X is N;
- iii. R^1 is a substituted or unsubstituted monocyclic or bicyclic aryl moiety;
- iv. R^2 is H or a substituted or unsubstituted C_{1-8} alkyl;
- v. Z is a 5-membered ring having N, V and W single/double bonded to N;
- vi. V is CR^7R^8 or CR^8R^8 .

The Examiner further states that the species in claims 101-106 of Application No. 10/914,974 anticipate the instantly claimed Formula I, and are analogous to some species recited in the instant claim 36. The Examiner further states that species in the instant claim 36 anticipate formula I of Application No. 10/914,974. This rejection is respectfully traversed. Application No. 10/914,974 has a filing date later than that of the instant application. As stated in the MPEP at Section 804:

If the provisional obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the two applications, the Examiner should withdraw that rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer.

Since all of the other rejections have been addressed and overcome, the only outstanding issue is the provisional obviousness-type double patenting rejection. Accordingly, it is respectfully requested that the Examiner withdraw this rejection and allow the application to issue.

Conclusion

For the foregoing reasons, it is submitted that the claims 1-2 and 25-36 are patentable over the teachings of the prior art relied upon by the Examiner. Accordingly, favorable reconsideration of the claims is requested in light of the preceding amendments and remarks. Allowance of the claims is courteously solicited.

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If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due under 37 C.F.R. § 1.17 and due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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